

## REMARKS

Claims 3-23 are pending. Claims 3, 6, 8-9, 13, 20, and 21 have been amended. Claims 1, 2, and 19 have been canceled without prejudice or disclaimer, and claims 15-19 are withdrawn as drawn to non-elected inventions. Claims 22-23 have been newly added. Support for the foregoing amendment can be found throughout the Specification and claims as originally filed, for example, at page 16, line 24 - page 18, line 19; page 26, lines 3-5; and page 35, lines 20-25. No new matter enters by way of the foregoing amendment.

### **I. Objections to Specification**

Applicants have amended the specification to add cross-reference to related applications. Support for this amendment can be found in the Combined Declaration and Power of Attorney for Patent Application previously submitted June 30, 2005 (copy and stamped postcard attached herewith).<sup>1</sup> Applicants respectfully request that the specification be amended such that Applicants can update the status of U.S. Appl. No. 09/638,508 in accordance with the Office's suggestions. Applicants respectfully request withdrawal of the objection.

### **II. Rejection under 35 U.S.C. § 112, Second Paragraph, Indefiniteness**

Claims 3-14, 20, and 21 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Office Action at pages 2-3. In rejecting the claims, the Office asserts that the terms "complements thereof, and fragments of either" render the claims indefinite. *Id.* at page 2. The Office further alleges that the terms "partially unaffected," "substantially unaffected," and "essentially unaffected" render the claims indefinite. *Id.* at page 3.

Applicant respectfully disagrees with the Office's rejections under 35 U.S.C. § 112, second paragraph. However, solely in order to facilitate prosecution, Applicant has amended the claims without prejudice or disclaimer. As such, Applicant respectfully asserts that the claim rejections are rendered moot.

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<sup>1</sup> Applicants note that the Combined Declaration and Power of Attorney for Patent Application was filed six months and nine days after the initial filing of the application.

Applicant respectfully submits that the Office's 35 U.S.C. § 112, second paragraph, indefiniteness rejection lacks any legal basis whatsoever. The scope of the subject matter claimed is clear. Breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, and if Applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. § 112, second paragraph. See MPEP § 2173.04.

Moreover, MPEP § 2173.02 states that the Office "should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the Office might desire." In making this determination, MPEP § 2173.02 goes on to clarify that definiteness of claim language must be analyzed, not in a vacuum, but in light of the disclosure, prior art, and ordinary skill in the pertinent art. Given the above standard, the claims are definite.

The specification refers to the term "complement" in numerous places. Specification, for example, at page 2, line 23; page 3, lines 7, 15, and 24; and page 8, lines 27-28. For instance, without being limited, the specification states that "the term complement of a nucleic acid sequence refers to the complement of the sequence along its complete length." Specification at page 8, lines 27-28. In light of this, Applicant respectfully submits that the metes and bounds of the invention are clear. As such, the claimed invention satisfies 35 U.S.C. § 112, second paragraph, and the rejections should be withdrawn.

The specification also refers to the term "fragments" in numerous places. Specification, for example, at page 2, line 23; page 3, lines 7, 16, and 25; and page 18, lines 7-13. As an example, without being limited, "[f]ragment nucleic acid molecules may consist of significant portion(s) of, or indeed most of, the nucleic acid molecules of the invention, such as those specifically disclosed." Specification at page 18, lines 7-8. In another non-limiting example, "a fragment nucleic acid molecule has a nucleic acid sequence that is at least 15, 25, 50, or 100 contiguous nucleotides of a nucleic acid molecule of the present invention." Specification at page 18, lines 9-13. Given this, Applicant respectfully submits that the metes and bounds of the

invention are clear. That is, given the disclosure, one of ordinary skill in the art at the time the invention was made would have the requisite skill to practice the invention commensurate in scope with the claims. As such, the claimed invention satisfies 35 U.S.C. § 112, second paragraph, and the rejections should be withdrawn.

Additionally, the specification refers to the terms “partially unaffected,” “substantially unaffected,” and “essentially unaffected” in numerous places. Specification, for example, at page 10, line 25 - page 11, line 12; page 11, line 29 - page 12, line 3; page 12, lines 10-11, 18-19, and 22-23; and page 13, lines 9-10, and 17-18. As an example, without being limited, “partially unaffected” can be “a level of an agent such as a protein or mRNA transcript in which the level of the agent that is partially unaffected is within 80%, more preferably within 65%, and even more preferably within 50% of the level at which it is found in a cell or organism that lacks a nucleic acid molecule capable of selectively reducing another agent.” Specification at page 11, lines 8-12. In another non-limiting example, “substantially unaffected” can be “a level of an agent such as a protein or mRNA transcript in which the level of the agent that is substantially unaffected is within 49%, more preferably within 35%, and even more preferably within 24% of the level at which it is found in a cell or organism that lacks a nucleic acid molecule capable of selectively reducing another agent.” Specification at page 11, lines 3-7. Further, without being limited, “essentially unaffected” can be the “level of an agent such as a protein or mRNA transcript that is either not altered by a particular event or altered only to an extent that does not affect the physiological function of that agent ... the level of the agent that is essentially unaffected is within 20%, more preferably within 10%, and even more preferably within 5% of the level at which it is found in a cell or organism that lacks a nucleic acid molecule capable of selectively reducing another agent.” Specification at page 10, line 25 - page 11, line 2. Given this, Applicant respectfully submits that the metes and bounds of the invention are clear. That is, given the disclosure, one of ordinary skill in the art at the time the invention was made would have the requisite skill to practice the invention commensurate in scope with the claims. As such, the claimed invention satisfies 35 U.S.C. § 112, second paragraph, and the rejections should be withdrawn.

Accordingly, for at least these reasons, it is submitted that the claims satisfy 35 U.S.C. § 112, second paragraph, and withdrawal of this rejection is respectfully requested.

**III. Rejection under 35 U.S.C. § 112, First Paragraph, Enablement**

Claims 3-14, 20 and 21 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way so as to enable those skilled in the art to make and/or use the invention commensurate in scope with the claims. Office Action at page 3. In rejecting the claims, the Office asserts that given the high level of unpredictability, the lack of working examples, and the absence of guidance with regard to choosing from a multitude of constructs to produce and select for the claimed soybean seeds, one of skill in the art would have to undergo undue experimentation in order to make and use the invention in a matter that is commensurate in scope with the claims. *Id.* at page 5.

Applicants respectfully disagree with the Office's rejections under 35 U.S.C. § 112, first paragraph. However, solely in order to facilitate prosecution, Applicant has amended the claims without prejudice or disclaimer. As such, Applicant respectfully asserts that the claim rejections are rendered moot.

At the outset, Applicant disagrees with the Office's assertion that "[t]he specification does not exemplify any plants encompassed by the claims, and it is unclear what the resultant phenotypes would be of a soybean plant transformed with any of the claimed constructs." Office Action at page 4. Applicant also disagrees with the Office's statement that "the specification does not teach a soybean plant transformed with any of the constructs set forth in the table much less any of the constructs encompassed by the claims, which include sequences that have greater than 85% identity to SEQ ID NO: 1, and complements and fragments thereof." *Id.* These assertions are in no way reflective of the breadth provided.

The specification provides for numerous soybean plants capable of producing soybean seeds with fatty acid compositions within levels of the claimed invention. Specification, for example, at Table I. Several of these soybean plants are transformed with constructs comprising SEQ ID NO: 1. Specification, for example, at page 43, line 23 - page 44, line 6; and Figure 2. For instance, soybean plants transformed with a pCGN5469 construct are capable of producing

seeds with more oleic acid than plants having a similar genetic background but lacking a nucleic acid molecule comprising SEQ ID NO: 1. As described in Table I, all 8 fatty acid composition data points isolated from soybean lines transformed with a pCGN5469 construct exhibit more oleic acid than plants having a similar genetic background but lacking a nucleic acid molecule comprising SEQ ID NO: 1. Alone, this is sufficient to render the claims enabled.

Moreover, pCGN5471 provides another example of a construct comprising SEQ ID NO: 1. Specification, for example, at Figure 3. Soybean plants transformed with a pCGN5471 construct are capable of producing seeds with more oleic acid than plants having a similar genetic background but lacking a nucleic acid molecule comprising SEQ ID NO: 1. As described in Table I, all 6 fatty acid composition data points isolated from soybean lines transformed with a pCGN5471 construct exhibit more oleic acid than plants having a similar genetic background but lacking a nucleic acid molecule comprising SEQ ID NO: 1. However, in rejecting the claims, the Office improperly ignores this point.

Applicant also disagrees with the Office's assertion that "the specification does not disclose any soybean plants with seeds having increased oleic acid." Office Action at page 4. As described above, soybean plants independently transformed with a pCGN5469 construct or a pCGN5471 construct are capable of producing seeds with more oleic acid than plants having a similar genetic background but lacking a nucleic acid molecule comprising SEQ ID NO: 1. Together, Table I describes 14 fatty acid composition data points isolated from soybean lines independently transformed with pCGN5469 or pCGN5471 constructs. **All 14 of these fatty acid composition data points exhibit more oleic acid than plants having a similar genetic background but lacking a nucleic acid molecule comprising SEQ ID NO: 1.** Again, even alone, this is sufficient to render the claims enabled.

In rejecting the claims, the Office further asserts that "the specification fails to provide guidance with regard to how to choose from the multitude of sequences encompassed by the claims, and how any given transformant would be evaluated." Office Action at page 4. Applicant disagrees. The specification provides for numerous constructs and transformed plants capable of producing soybean seeds with fatty acid compositions within levels of the claimed invention. Specification, for example, at Figures 2-3 and Table I. Moreover, Tables I - III

provide fatty acid composition data such that one of skill in the art would have the ability to choose transformed plants with a desired fatty acid profile without undue experimentation. Given this, one of skill in the art at the time the invention was made would have the ability to practice the claimed invention in a manner that is commensurate in scope with the claims without undue experimentation.

Applicant disagrees with the Office's reliance on Lee *et al.* (*Plant Physiology* 119: 989-1000, 1999) ("Lee") to allegedly show that the claims are not enabled. Office Action at page 4. In rejecting the claims, the Office asserts that Lee "teach the unpredictability of modifying plant gene expression using sequences that are not identical to endogenous sequences." *Id.* The Office further states that "the modification of plant lipid composition or any other phenotypic change by transforming a plant with any of the nucleic acids encompassed by the claims is highly unpredictable." *Id.* However, these statements by the Office ignore the fatty acid composition data from seeds of soybean lines transformed with pCGN5469 and pCGN5471 constructs.

Even assuming, *arguendo*, that the Office's statements are true, the Office has misapplied Lee's teaching of "unpredictability" to the present invention. The Office appears to use Lee to allege the unpredictability of the resultant seed fatty acid composition in transformed seeds and plants. However, Applicant is not claiming the method by which the invention was created; rather, the claims are directed to plants. Here, Applicant is claiming compositions, namely, soybean plants transformed with nucleic acid molecules including a genome comprising SEQ ID NO: 1, and such plants were achieved by the Applicant. Given this, one of skill in the art would not interpret Lee in such a manner that would shed doubt on the enablement of the claimed invention.

Moreover, given the teachings of the specification, one of skill in the art would have the ability to make nucleotide substitutions to SEQ ID NO: 1 without undue experimentation. Performing routine and well-known steps cannot create undue experimentation even if it is laborious. *See In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 218-219 (C.C.P.A. 1976). That is, one of skill in the art would have the ability to transform a soybean plant with a nucleic acid molecule comprising a polynucleotide having at least 95% identity to SEQ ID NO: 1 with

the expectation that seeds isolated from those plants would have higher oleic acid than plants having a similar genetic background but lacking a nucleic acid molecule comprising SEQ ID NO: 1.

Given the disclosure, Applicant respectfully submits that one of ordinary skill in the art would have the requisite skill to create a plant transformed with a nucleic acid molecule comprising SEQ ID NO: 1, wherein the transformed plant is capable of producing seeds with more oleic acid than plants having a similar genetic background but lacking a nucleic acid molecule comprising SEQ ID NO: 1. Applicant has sufficiently described the claimed invention such that one of skill in the art in light of the specification would be able to practice the invention commensurate in scope with the claims. In sum, such disclosure provides adequate direction, including working examples, to teach the skilled artisan how to make and use the claimed invention without undue experimentation.

It is submitted that Applicant has provided considerable direction and guidance, and has presented working examples such that it is well within the level of ordinary skill in the art to practice the invention without undue experimentation. The Office has not provided sufficient evidence to discredit the teaching in the specification. Rather, the Office suggests inapplicable and generalized observations.

Accordingly, for at least these reasons, it is submitted that the claims are sufficiently enabled under 35 U.S.C. § 112, first paragraph, and withdrawal of this rejection is respectfully requested.

## CONCLUSION

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Office is respectfully requested to withdraw the outstanding rejections of the claims, and to pass this application to issue. The Office is encouraged to contact the undersigned at (202) 942-5186 should any additional information be necessary for allowance.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Kristan Lansbery", with a stylized, flowing script.

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Date: May 27, 2008

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Atty. Docket No.:

16518.162

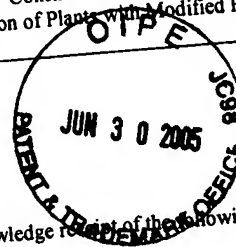
Date: June 30, 2005

**IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)**

Applicants: Joanne J. FILLATTI  
Serial No.: 10/518,753  
Int'l Filing Date: June 20, 2003  
Title: Nucleic Acid Sequences and Methods of Use for the Production of Plants with Modified Polyunsaturated Fatty Acids

Art Unit: To Be Assigned  
Examiner: To Be Assigned  
Confirmation No.: 8074

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Sir:

Please place the U.S. Patent & Trademark Office receipt stamp hereon to acknowledge receipt of the following:

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4. Combined Decl'n & Power of Atty. for Patent Appln., executed by Joanne J. FILLATTI (3 pp.); and
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## Combined Declaration and Power of Attorney for Patent Application

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter that is claimed and for which a patent is sought on the invention entitled **Nucleic Acid Sequences and Methods of Use ofr the Production of Plants with Modified Polyunsaturated Fatty Acids**, the specification of which is attached hereto unless the following box is checked:

☒ was filed on June 20, 2003 as International Application No. PCT/US2003/019445; and deposited as U.S. Serial No. 10/518,753 on December 21, 2004;

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information that is material to patentability as defined in 37 C.F.R. § 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT international application, which designated at least one country other than the United States listed below, and have also identified below any foreign application for patent or inventor's certificate, or PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

Priority Claimed

\_\_\_\_\_  
(Application No.)      (Country)      (Day/Month/Year Filed)

☐ Yes    ☐ No

\_\_\_\_\_  
(Application No.)      (Country)      (Day/Month/Year Filed)

☐ Yes    ☐ No

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below.

\_\_\_\_\_  
(Application No.)      (Filing Date)

\_\_\_\_\_  
(Application No.)      (Filing Date)

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or under § 365(c) of any PCT international application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose information that is material to patentability as defined in 37 C.F.R. § 1.56 that became available between the filing date of the prior application and the national or PCT international filing date of this application.

<u>10/176,149</u> (Application No.)	<u>June 21, 2002</u> (Filing Date)	<u>Pending</u> (Status - patented, pending, abandoned)
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<u>                    </u> (Application No.)	<u>                    </u> (Filing Date)	<u>                    </u> (Status - patented, pending, abandoned)
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<u>                    </u> (Application No.)	<u>                    </u> (Filing Date)	<u>                    </u> (Status - patented, pending, abandoned)
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I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

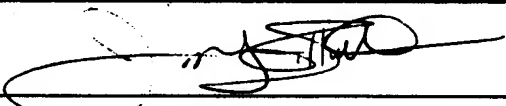
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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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